

### **Amendments to the Drawings**

In response to the Objection to the Drawings, please delete the previously added Figs. 1-4 and insert Figs. 1-4 submitted herewith.

### Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, new claim 27 has been added, so that claims 1-19, 24, and 27 will be pending upon entry of the present amendment.

Previously, Applicants submitted Figs. 1-4 and provided a Brief Description of the Drawings in response to an objection to the drawings under 37 CFR 1.83(a) for failing to show each and every feature of the invention specified in the claims. The new Figs. 1-4 were subsequently objected to under 35 U.S.C. § 132(a) for introducing new matter into the disclosure. In response, Applicants have cancelled the previously filed subject matter and submitted herewith a brief description and revised Figs. 1-4 which comply with the requirements of 35 U.S.C. § 132(a). Regarding Fig. 2, the carrier layer 2 is shown having the same size as the polymer film 1. Regarding Fig. 3, a generic bag is shown having an opening. Regarding Fig. 5, the dispenser/holder 4 is shown as a outline. Entry of the foregoing and withdrawal of the record new matter objection is respectfully requested.

Claim 18 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Examiner states that it is unclear how an inflatable bag is to be used as a carrier film for the polymer film. Applicants note page 13, paragraph 3 of the specification which describes one embodiment wherein the polymer film is applied to the tooth surface using the carrier film. After curing, the carrier film is removed. Thus, there are two layers, a polymer film layer and a carrier film layer attached to each other. The polymer film is on the side that is applied to the tooth surface and the carrier film is on the other side. Once the polymer film is cured to the tooth surface, the carrier film layer is peeled off. Page 13, paragraph 4 of the specification describes a further embodiment wherein the carrier film is provided in the form of an inflatable film bag. Again, there are two layers, the polymer film is on the side that is applied to the tooth surface and the carrier film bag is on the other side. The polymer film is applied to the tooth surface, for example, in the space between two teeth. The film bag is then inflated and

presses the polymer film to the tooth surface. After curing, the carrier film bag is peeled off in the manner noted above.

Accordingly, the claimed film bag is described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Withdrawal of the record rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 1, 17, 19, and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,482,464 to Shimosawa et al. (“Shimosawa”). This rejection is respectfully traversed.

Shimosawa is said to disclose a dental resin sheet for coating tooth surfaces formed of a flexible solid polymer film which is shaped around a tooth and then further polymerized with light to coat the surface of the tooth (column 4, lines 1-6). The Shimosawa dental resin sheet is said to inherently include a continuous polymer network.

Applicants disagree. Shimosawa does not disclose a solid film having a continuous polymer network. Rather, Shimosawa discloses a dental resin sheet in the form of a layered sheet which consists of light curing dental resin layers laminated one on top of another. No details are given as to the chemical nature of the resin, and there is certainly no explicit indication that a continuous polymer network is present. For the reasons given below, Applicants submit that the resin sheet according to Shimosawa consists of the same kind of material as described by Cornell.

The Examiner alleges that the dental resin sheet according to Shimosawa would inherently include a continuous polymer network without giving specific reasons in support. However, Applicants request that the Examiner explain why in the absence of any details regarding the chemical nature of the resin sheet described by Shimosawa such resin sheet could nevertheless be considered to inherently include a continuous polymer network.

Assuming the Examiner’s belief that the resin sheet according to Shimosawa would include a continuous polymer network has been prompted by the term “sheet”, which could suggest a material having a certain degree of two-dimensional strength, it should be noted that in the field of dental resins the term “sheet” is often used for uncured putty or dough-like materials consisting of a liquid phase of monomer molecules thickened by a filler.

For instance, there is a dental material sold by Dentsply under the name of Triad<sup>®</sup> Transheet<sup>™</sup> Material, which is provided in the form referred to as “sheets”. However, as can be seen from the corresponding Material Safety Data Sheet, copy enclosed, this material is actually “doughy” in the uncured state (Section 9, Physical and Chemical Properties). Thus, it is clear that dental sheets do not inherently include a continuous polymer network.

Accordingly, Shimosawa fails to anticipate claims 1, 17, 19, and 24 since a claim element is lacking. Withdrawal of the record rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1-6, 8, 9, 11, 16, 17, and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shimosawa in view of U.S. Patent No. 3,265,202 to Cornell (“Cornell”). This rejection is respectfully traversed.

Shimosawa has been acknowledged as failing to disclose the particular composition of the polymerizable film. Cornell is cited for disclosing a flexible dental polymer film comprising a non fiber-reinforced flexible film layer which comprises polymerizable groups capable of further polymerization, the film can be shaped around a tooth and cured by polymerization (column 1, line 16 and column 1, line 37). Further, Cornell is also cited for disclosing that acrylates, methacrylates and polyurethanes are commonly used as dental materials. The Examiner considers that to have merely selected common polymerizable dental materials for the dental material of Shimosawa as taught by Cornell would have been obvious to one of ordinary skill in the art.

It is the Applicants position that the resin sheet disclosed by Shimosawa is a dough or putty material similar to the one described by Cornell, which has already been acknowledged not to anticipate the solid polymer film of the invention. More particularly, the Examiner has apparently acknowledged that Cornell does not disclose a solid film having a continuous polymer network in addition to polymerizable groups. Rather, Cornell describes a putty composition wherein isolated polymer particles are dispersed in a liquid phase of monomer molecules. This material is essentially a thickened liquid.

It is further noted that in order to assure that the surface of the sheet is kept smooth, the resin sheet according to Shimosawa has to be protected by a protective film (column 3, lines 36-39). This supports Applicants position that the resin sheet is not a solid polymer film

within the meaning of claim 1 (which would not require such protection), but rather a putty material, such as that described by Cornell.

Accordingly, there is no indication, either explicitly or implicitly, that the dental sheet described by Shimosawa is a solid film having a continuous polymer network as required by present claim 1. Consequently, at least for this reason, the proposed combination of the teachings of Shimosawa and Cornell fail to teach or suggest a solid film having a continuous polymer network. Accordingly, the subject matter of the present claims is not rendered obvious by Shimosawa in view of Cornell.

Withdrawal of the record rejection of claims 1-6, 8, 9, 11, 16, 17, and 19 under 35 U.S.C. § 103(a) as being obvious over Shimosawa in view of Cornell is respectfully traversed.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of U.S. Patent No. 5,154,762 to Mitra et al. ("Mitra"). This rejection is respectfully traversed.

Mitra is relied upon for the disclosure of an initiator in microencapsulated form. However, as set forth in detail above, Shimosawa and Cornell lack a teaching or suggestion of the dental polymer film of present claim 1. In particular, none of the cited documents provides any teaching or motivation to use a flexible dental polymer film or membrane comprising polymerizable groups capable of further polymerization. Therefore, the subject matter of claim 7 is not rendered obvious by the teachings of Shimosawa and Cornell in combination with Mitra. Claim 7 is patentable for at least the reasons that claim 1 from which it depends is patentable.

Withdrawal of the record rejection of claim 7 under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of Mitra and allowance of claim 7 is respectfully requested.

Claims 10, 12, 13, and 24 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of U.S. Patent No. 6,039,569 to Prasad et al. ("Prasad"). This rejection is respectfully traversed.

The Prasad disclosure is cited for teaching a dental polymer film having an antioxidant, a primer, and an adhesive. However, as set forth in detail above, Shimosawa and Cornell lack a teaching or suggestion of the dental polymer film of present claim 1. In particular, none of the cited documents provides any teaching or motivation to use a flexible dental polymer

film or membrane comprising polymerizable groups capable of further polymerization. Therefore, the subject matter of claims 10, 12, 13, and 24 is not rendered obvious by the teachings of Shimosawa and Cornell in combination with Prasad. These claims are patentable for at least the reasons that claim 1 from which they depend is patentable.

Therefore, withdrawal of the record rejection of claims 10, 12, 13, and 24 under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of Prasad and allowance of said claims is respectfully requested.

Claims 14 and 15 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of U.S. Patent No. 6,197,410 to Vallittu et al. ("Vallittu"). This rejection is respectfully traversed.

The Examiner contends that it would have been obvious to coat one side of the material of Vallittu with an anti-adhesive. However, as set forth in detail above, Shimosawa and Cornell lack a teaching or suggestion of the dental polymer film of present claim 1. In particular, none of the cited documents provides any teaching or motivation to use a flexible dental polymer film or membrane comprising polymerizable groups capable of further polymerization. Thus, claims 14 and 15 depend from claim 1 and are not obvious in view of the teachings of Shimosawa and Cornell in view of Vallittu for at least the reasons noted above with respect to claim 1.

Withdrawal of the record rejection of claims 14 and 15 under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of Vallittu and allowance of said claims is respectfully requested.

Claim 18 stands rejected under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of Karazivan (WO 01/93774). This rejection is respectfully traversed.

The Examiner contends that Karazivan teaches a film detachably held on a carrier film in the form of an inflatable film bag and that it would have been obvious to modify the film of Shimosawa having the carrier film of Karazivan in order to better adapt the dental film to the applied surface. However, as set forth in detail above, Shimosawa lacks a teaching or suggestion of the dental polymer film of present claim 1. In particular, none of the cited documents provides any teaching or motivation to use a flexible dental polymer film or membrane

comprising polymerizable groups capable of further polymerization. Claim 18 depends from claim 1 and is not obvious in view of the teachings of Shimosawa and Cornell in view of Karazivan for at least the reasons noted above with respect to claim 1.

Withdrawal of the record rejection of claim 18 under 35 U.S.C. § 103(a) as being obvious over Shimosawa and Cornell in view of Karazivan and allowance of claim 18 is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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## MATERIAL SAFETY DATA SHEET

### SECTION 1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: Triad® TransSheet™ Light Cure Material  
Product Number: 89270-89276, 90130  
MSDS Code Number: 86

Manufacturer: Dentsply Prosthetics  
Address: 570 West College Ave.  
York, PA 17405-0872  
Information Telephone Number: 717-845-7511  
Emergency Telephone Number: 800-424-9300 Chemtrec

Product Use: Resin used in removable dental appliances.

Date of Last Revision: May 24, 2006

### SECTION 2 COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Polymethylmethacrylate	Proprietary	20-40	Xi R36/38, R43
Amorphous Precipitated Silica	112945-52-5/231-545-4	5-10	Not Applicable
Dichlorodimethyl Silane-, reaction products with silica	68611-44-9/271-893-4	10-20	Not Applicable
Acrylate Urethane Oligomer	Proprietary	5-10	Xi R36/38, R43
Ethoxylated Trimethylol Propane Triacrylate	28961-43-5/NLP	1-5	Xi R36, R43
Urethane Dimethacrylate	72869-86-4/276-957-5	40-80	R52/53

See Section 16 for further information on EU Classification.

### SECTION 3 HAZARDS IDENTIFICATION

Emergency Overview: CAUTION! May cause eye and skin irritation. May cause skin sensitization.

EU Preparation Classification (1999/45/EC): Xi; R36/38, R43, R52/53

### SECTION 4 FIRST AID MEASURES

Eye Contact: Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention.

Skin Contact: Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use. (Discard contaminated shoes).



Ingestion: If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

Inhalation: If irritation develops, remove to fresh air. Get medical attention if symptoms persist.

## SECTION 5 FIRE FIGHTING PROCEDURES

Extinguishing Media: Water fog, foam, carbon dioxide, water spray or dry chemical.

Firefighting Procedures: Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus. Cool exposed intact containers with water spray.

Unusual Fire/Explosion Hazards: High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes.

Known or Anticipated Hazardous Products of Combustion: Acrid fumes, carbon oxides, and methylmethacrylate.

## SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Exposure to sunlight or artificial light will cause the paste to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

Personal Precautions: Avoid contact with skin, eyes or clothing.

Environmental Precautions: Prevent entry into sewers and waterways.

## SECTION 7 HANDLING AND STORAGE

Handling: Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in a tightly closed container in a cool, well ventilated location away from incompatible materials. Do not store near high temperatures or ignition sources. Prevent contact with moisture. Refrigeration prolongs shelf life. Store away from food or beverages.

## SECTION 8 EXPOSURE CONTROLE/PERSONAL PROTECTION

Occupational Exposure Limits:

Polymethylmethacrylate	None Established
Amorphous Precipitated Silica	3 mg/m <sup>3</sup> (respirable fraction) TWA ACGIH TLV 10 mg/m <sup>3</sup> (inhalable) TWA ACGIH TLV 5 mg/m <sup>3</sup> (respirable fraction) TWA OSHA PEL 15 mg/m <sup>3</sup> (total dust) TWA OSHA PEL
Dichlorodimethyl Silane-, reaction products with silica	6 mg/m <sup>3</sup> TWA manufacturer recommended
Acrylate Urethane Oligomer	None Established
Ethyoxylated Trimethylol Propane Triacrylate	None Established

Urethane Dimethacrylate	None Established
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**Engineering Controls:** Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits or when grinding polymerized (cured) materials.

**Personal Protective Equipment:**

**Eye Protection:** Chemical safety glasses or chemical splash goggles.

**Skin Protection:** Wear impervious gloves such as rubber to prevent skin contact.

**Respiratory Protection:** None under normal use conditions. If the product is heated and ventilation is inadequate, wear a NIOSH approved respirator appropriate for the exposure conditions.

**Other Protective Clothing or Equipment:** Impervious clothing as needed to prevent contact. A safety shower and eye wash should be available in the immediate work area.

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

**Appearance and Odor:** Colorless or pink doughy material in the uncured state.

Colorless or clear pink hard plastic when cured.

**Boiling Point:** N/A (polymerizes)

**Melting Point:** N/A

**Freezing Point:** <-40°C(<-40°F)

**Specific Gravity:** 1.2

**Solubility in Water:** Negligible

**pH:** Not determined

**Vapor Pressure (mmHg):** <1

**Vapor Density:** >1

**Evaporation Rate:** Not available

**Viscosity:** Not determined

**% Volatile by Volume:** Negligible

**Flashpoint:** Not applicable

**Flammable Limits in Air:**

**Autoignition Temperature:** Not applicable

**LEL:** N/A

**UEL:** N/A

## SECTION 10 STABILITY AND REACTIVITY

**Stability:** Stable

**Conditions to Avoid:** Polymerizes to form a hard plastic in 6 hours at 60°C(140°F) with low exotherm.

**Incompatibility with Other Materials:** Oxidizing agents, reducing agents, tertiary amines, heavy metals, peroxides, and free radical initiators. Avoid excessive heat, flames, ignition sources and direct sunlight.

**Hazardous Decomposition Products:** Acid fumes, carbon oxides, and methylmethacrylate.

## SECTION 11 TOXICOLOGICAL INFORMATION

**Potential Health Effects:**

**Eyes:** May cause irritation, redness and tearing.

**Skin:** May cause irritation, redness, rash and swelling. May cause allergic skin reaction (sensitization).

**Ingestion:** None expected under normal use conditions.

**Inhalation:** None expected under normal use.

**Chronic Health Effects:** None expected under normal use.

**Carcinogenicity:** None of the components are listed as possible carcinogens by NTP, IARC or OSHA.

**Medical Conditions Aggravated by Exposure:** Individuals with pre-existing skin disorders may be at increased risk from exposure.

**Acute Toxicity Data:**

Polydimethylmethacrylate No data available

Amorphous Precipitated Silica Oral Rat LD50: >10,000 mg/kg; Inhalation Rat LC50: >0.139 mg/l/4h;  
Skin Rabbit LD50: >5000 mg/kg

Dichlorodimethyl Silane-, reaction products with silica	Oral rat LD50: >5000 mg/kg
Ethoxylated Trimethylol Propane Triacrylate	No data available
Acrylate Urethane Oligomer	No data available
Urethane Dimethacrylate	Oral Rat LD50: >2000 mg/kg

## SECTION 12 ECOLOGICAL INFORMATION

Polymethylmethacrylate	No data available
Amorphous Precipitated Silica	24h/EC50 Daphnia Magna: >10,000 mg/l; 96h/LC50 Zebra Fish: >10,000 mg/l
Dichlorodimethyl Silane-, reaction products with silica	No data available
Ethoxylated Trimethylol Propane Triacrylate	No data available
Acrylate Urethane Oligomer	No data available
Urethane Dimethacrylate	96h/LC50 zebra fish: 10.1 mg/l, not readily biodegradable

## SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations. Exposure to sunlight or artificial light will cause the material to polymerize into a hard plastic.

## SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated  
DOT Hazard Class: N/A  
UN Number: N/A  
DOT Labels Required (49CFR172.101): N/A

IATA Shipping Name: Not Regulated  
IATA Hazard Class: N/A  
UN Number: N/A  
IATA Hazard Labels Required: N/A

IMDG Shipping Name: Not Regulated  
IMDG Class: N/A  
UN Number: N/A  
IMDG Label: N/A

## SECTION 15 REGULATORY INFORMATION

### U.S. FEDERAL REGULATIONS:

**CERCLA:** Report spills required under federal, state and local regulations.

### SARA TITLE III:

Hazard Category For Section 311/312: Acute Health, Chronic Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and not subject to chemical notification requirements.

#### **U.S. STATE REGULATIONS**

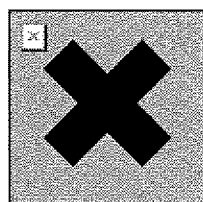
California Proposition 65: This product contains the following substances known to the State of California to cause cancer: None

#### **INTERNATIONAL REGULATIONS:**

Canadian WHMIS Classification: Class D Division 2B (Eye and skin irritant, skin sensitizer)

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

European Community Labeling:



Irritant

R36/38 Irritating to eyes and skin  
R43 May cause sensitization by skin contact.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention  
S24/25 Avoid contact with skin and eyes.  
S36/37 Wear suitable protective clothing and gloves.  
S61 Avoid release to environment. Refer to safety data sheets

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

### **SECTION 16 OTHER INFORMATION**

HMIS Hazard Rating:

Health – 2      Fire Hazard – 1      Reactivity – 1

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

Xi Irritant

R36 Irritating to eyes.

R36/38 Irritating to eyes and skin.

R43 May cause sensitization by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Revision Date: 5/24/2006

Supersedes: 6/25/1997